

To Whom It May Concern:

DeRoyal Foley Catheters with Temperature Sensors have been tested for safe use in magnetic resonance environments at 1.5 and 3.0 Tesla according to ASTM International F2052, “Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.”

The testing at 1.5 Tesla and 3.0 Tesla was completed in 2018. The results demonstrate that the catheters are “MR Conditional,” according to ASTM International F2503, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.” This designation means the device has demonstrated safety in an MR environment with defined conditions. These conditions are defined in the attached pages.

Please consult the Instructions for Use and the attached guidelines prior to using the device.



MRI Safety Information



MR Conditional

Non-clinical testing demonstrated that the Foley Catheter with Temperature Sensor is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, only
- Maximum spatial gradient magnetic field of 1,500 Gauss/cm (10.5 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the Foley Catheter with Temperature Sensor is expected to produce a maximum temperature rise of 2.1°C after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Foley Catheter with Temperature Sensor extends approximately 20 mm from this device when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.

Warning: Closely follow all specific conditions to permit the MRI examination to be conducted safely in a patient with this device. Any deviation from the stated conditions may result in a serious injury to the patient. This device should never be connected to a cable and/or connected to a temperature monitor during an MRI procedure. Failure to follow this requirement may result in serious injury to the patient and/or damage to the device.

Important Requirements to Ensure Patient Safety During MRI

Special Instructions: The position of the wire of the Foley Catheter with Temperature Sensor has an important effect on the amount of heating that may develop during an MRI examination. Accordingly, the wire of the Foley Catheter with Temperature Sensor must be positioned in a straight configuration down the center of the patient table (i.e., down the center of the MR system without any loop) to prevent possible excessive heating associated with an MRI examination.

Additional safety instructions include the following:

- Ensure the Foley Catheter with Temperature Sensor is not connected to a cable and/or connected to a temperature monitor before placing the patient in an MR system.
- Remove all electrically conductive material from the bore of the MR system that is not required for the procedure (i.e., unused surface coils, cables, etc.).
- Keep electrically conductive material, including the Foley Catheter with Temperature Sensor, that must remain in the bore of the MR system from directly contacting the patient by placing thermal and/or electrical insulation (including air) between the conductive material and the patient.
- Position the Foley Catheter with Temperature Sensor wire in a straight configuration down the center of the patient table to prevent cross points and conductive coils or loops.
- The wire and connector of the Foley Catheter with Temperature Sensor should not be in direct contact with the patient during the MRI examination. Position the device, accordingly.
- Provide the patient with a means and instructions to immediately alert the MR system operator of problems (e.g., heating, shocks, etc.) so the operator can immediately terminate the MRI procedure, if needed.
- Monitor the patient continuously during the MRI procedure and be prepared to respond in the event of an emergency.
- Do not use with unconventional or non-standard MRI techniques.

